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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,271	01/15/2002	Milton B. Yatvin	90,663-QQ	9913

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/050271

Applicant(s)

Nation step

Examiner

Kaff

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/15/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-25 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-25 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The ~~proposed~~ drawing ~~correction~~, filed on 1/15/02 ~~is~~ ^{are} ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on ~~1/15/02~~ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims examined on the merits are 1-25, which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

5 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10 Claims 11-16, 18, 19, 21, 22, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 and claims dependent thereon are confusing and unclear
15 by claim 11 reciting "optionally" in line 1. Optionally claiming conditions, makes unclear metes and bounds of the claims that are to be patentably limiting. Additionally, if the polar lipid that is optional is not present, claim 11 does not further limit claim 1 and is an improper dependent claim. It is suggested that "optionally" be
20 replaced with --- further ---.

Claims 18 and 19, and 21 and 22 are confusing and unclear by requiring killing a microorganism and treating a microbial infection with the compositions of claims 3 and 5, respectively, since claims 3 and 5 are not limited to an antimicrobial peptide or drug, but
25 encompass an antiviral peptide or drug. An antiviral peptide or drug will not kill a microorganism. In line 2 of claim 18 and line 3 of claim 21, it is suggested that --- when the composition contains an

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antimicrobial peptide --- be inserted after "3". In line 2 of claim 19 and line 3 of claim 22, it is suggested that --- when the composition contains an antimicrobial drug --- be inserted after "5".

Double Patenting

5 A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical
10 subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

15 A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

20 Claims 17 and 21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3 and 19, respectively, of prior U.S. Patent No. 5,543,391. This is a double patenting rejection.

When the biologically active compound of claim 1 is a defensin peptide as in claim 17, the composition is the same as required by
25 claim 3 of the patent that requires a defensin peptide. When carrying out the method of claim 21, the antimicrobial peptide of the composition of claim 3 would be required for treating a microbial infection, and the method of claim 21 is the same as the method of claim 19 of the patent that requires treating a microbial infection
30 with an antimicrobial peptide.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy

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reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 5 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

10 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

15 Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 25-73 of U.S. Patent No. 6,339,060 B1 or claims 24-51 of U.S. Patent No. 6,063,759 or claims 1-25 of U.S. Patent No. 5,840,674 or claims 1-19 of U.S. Patent No. 5,543,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because coating porous particles impregnated with a biologically 25 active compound with an organic coating compound would have been obvious from the claims of the patents that require coating porous or nonporous particles containing a prodrug or an antimicrobial drug, with a coating material. It would have been obvious to use a biologically active compound rather than a prodrug of the compound.

30 The claims are free of the prior art.

Specification

The disclosure is objected to because of the following informalities: the abstract should be replaced with the abstract

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contained by U.S. Patent No. 6,339,060 B1 that issued from parent application 09/573,497.

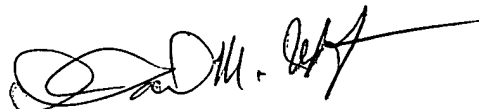
Appropriate correction is required.

Any inquiry concerning this communication or earlier
5 communications from the examiner should be directed to David M. Naff
whose telephone number is 703-308-0520. The examiner can normally be
reached on Monday-Friday about 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,
the examiner's supervisor, Mike Wityshyn can be reached on 703-308-
10 4743. The fax phone number for the organization where this
application is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this
application or proceeding should be directed to the receptionist whose
telephone number is 703-308-0196.

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David M. Naff
Primary Examiner
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DMN
8/25/03